K981677

AUG 27 1999

510(k) Summary

Influence, Inc.'s Repose™ Bone Screw System

Company Name:

Influence, Inc.
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Submitter's Name and Contact Person:

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or

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Date Prepared:

May 11, 1998

Trade/Proprietary Name:

Repose™ Bone Screw System

Classification Name:

The Repose Bone Screw System has not yet been classified.

Predicate Devices:

Repose™ Bone Screw System:

- Sleep-In™ Bone Screw System (K972023)
- In-Fast™ Bone Screw System (K970292)
- Mitek GII Anchor (K920213)

Performance Standards:

No performance standards applicable to the bone screw systems have been established by the FDA. However, the titanium alloy 6AL-4V Eli alloy used to manufacture the Repose Bone Screw meets the chemical and mechanical requirements in voluntary standards established by ASTM (F136-84).

Intended Use:

The Repose™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is also suitable for the performance of a hyoid procedure. It is indicated for the treatment of obstructive sleep apnea ("OSA") and/or snoring.

System Description:

The Repose™ Bone Screw System consists of three main components: a bone screw attached to surgical suture material, a bone screw inserter, and a suture passer. The Repose™ Bone Screw is a sharp tipped, small diameter titanium screw with polypropylene monofilament no. 1 suture crimped into its base.

The Repose™ Bone Screw Inserter is a disposable, battery operated, single use device. The Repose™ Suture Passer is designed to assist in passing the suture through the floor of the tongue in a tongue base advancement procedure or through the neck during a hyoid suspension procedure.

Technological Characteristics and Substantial Equivalence:

The performance characteristics of the Repose™ Bone Screw System has been tested and approved through a series of *in vitro* and *in vivo* studies, previously submitted under 510(k): K972023 for Influence Inc's Sleep-In™ Bone Screw System.

The Repose™ Bone Screw System, like its predicate devices the Sleep-In™ Bone Screw System, the In-Fast™ Bone Screw System and the Mitek GII Anchor, is based on suspending soft tissue to fixed bone by means of sutures attached to bone screw.

In respect to the procedure, the Repose™ System procedure is based upon well accepted and commonly used procedures like *Hyoid Bone Suspension, Chin Osteotomy* and *Genioglossal Advancement* for the treatment of OSA and/or snoring.

The Repose™ Bone Screw System is substantially equivalent to the Sleep-In™ Bone Screw System with respect to the intended use for the treatment of OSA and/or snoring by means of repositioning of the tongue and to the commonly

accepted practice of *Hyoid Bone Suspension* by means of tongue base advancement via the hyoid bone which is attached to the tongue base musculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Influence, Incorporated
C/O Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K981677
Trade Name: Repose Bone Screw System
Regulatory Class: Unclassified
Product Code: LRK
Dated: June 3, 1999
Received: June 3, 1999

Dear Mr. Kahan

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K981677

Device Name: Repose™ Bone Screw System

Indications for Use: The Repose™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is also suitable for the performance of a hyoid suspension procedure as an adjunct to tongue base suspension. It is indicated for the treatment of obstructive sleep apnea ("OSA") and/or snoring.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Dental, Infection Control
and General Hospital Devices
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Prescription Use ✓ OR Over the Counter